FEB 2 3 2004

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K033820

1. **Submitter's Identification:**

   Microlife Intellectual Property GmbH, Switzerland
   Max Schmidheiny-Strasse 201
   9435 Heerbrugg / Switzerland

   Date Summary Prepared: December 8, 2003

   Contact: Mr. Gerhard Frick

2. **Name of the Device:**

   Microlife Digital Infrared Forehead Thermometer, Model FR1DM1

3. **Predicate Device Information:**

   Microlife Digital Infrared Ear Thermometer, Model IR1DE1, K#020725

4. **Device Description:**

   The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is an ectronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on the LCD.

   Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

   The Microlife Digital Infrared Forehead Thermometer, consists mainly of five parts:

   a) IR Thermopile Sensor
   b) ASIC
   c) E^2PROM IC

d) LCD and Blacklight
e) Key*2, Buzzer*1

5. **Intended Use:**

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

6. **Comparison to Predicate Devices:**

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1 in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc.,

The major difference between the Microlife Infrared Forehead Thermometer and the predicate device is the measuring site. The predicate device is measuring ear temperature while the subject device is measuring forehead temperature.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965-98, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted using the Microlife Infrared forehead thermometer FR1DM1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per Microlife clinical test protocol for infrared forehead thermometer.

9. **Conclusions:**

The Microlife Infrared Forehead Thermometer, Model FR1DM1, has the same intended use and similar technological characteristics as the Microlife Infrared Ear thermometer Model IR1DE1. Moreover, bench testing contained in this

submission supplied demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Infrared Forehead Thermometer, Model FR1DM1, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2004

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K033820
Trade/Device Name: Microlife Digital Infrared Forehead Thermometer, Model FR1DM1
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 8, 2003
Received: December 9, 2003

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K033820

Device Name: Microlife Digital Infrared Forehead Thermometer, Model FR1DM1

Indications For Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033820

Prescription Use _____ **OR** **Over-The Counter Use** ✓
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**